

## United States Patent and Trademark Office

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/520,779	10/13/2005	Margaret A Pericak-Vance	5405-271	2423
	7590 02/26/200 L SIBLEY & SAJOVE	EXAMINER		
PO BOX 37428			POHNERT, STEVEN C	
RALEIGH, NC 27627			ART UNIT	PAPER NUMBER
			1634	
			<del>*                                    </del>	
SHORTENED STATUTOR	Y PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE	
31 DAYS		02/26/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

	Application No.	Applicant(s)	
	10/520,779	PERICAK-VANCE ET AL.	
Office Action Summary	Examiner	Art Unit	
·	Steven C. Pohnert	1634	
The MAILING DATE of this communication Period for Reply	appears on the cover sheet wit	the correspondence address	
A SHORTENED STATUTORY PERIOD FOR RE WHICHEVER IS LONGER, FROM THE MAILING  - Extensions of time may be available under the provisions of 37 CFr after SIX (6) MONTHS from the mailing date of this communication  - If NO period for reply is specified above, the maximum statutory period to reply within the set or extended period for reply will, by st Any reply received by the Office later than three months after the meanned patent term adjustment. See 37 CFR 1.704(b).	B DATE OF THIS COMMUNIC R 1.136(a). In no event, however, may a re- riod will apply and will expire SIX (6) MONT atute, cause the application to become ABA	ATION.  bly be timely filed  HS from the mailing date of this communication.  NDONED (35 U.S.C. § 133).	
Status			
1) Responsive to communication(s) filed on 1.  2a) This action is <b>FINAL</b> . 2b) 1.  3) Since this application is in condition for alloclosed in accordance with the practice under the condition.	This action is non-final.  wance except for formal matte	-	
Disposition of Claims			
4) ☐ Claim(s) 1-10,15-19 and 29-33 is/are pendid 4a) Of the above claim(s) is/are withen 5) ☐ Claim(s) is/are allowed. 6) ☐ Claim(s) is/are rejected. 7) ☐ Claim(s) is/are objected to. 8) ☐ Claim(s) 1-10,15-19 and 29-33 are subject	drawn from consideration.	quirement.	
Application Papers			
9) The specification is objected to by the Exam	niner.		
10) The drawing(s) filed on is/are: a)		y the Examiner.	
Applicant may not request that any objection to	the drawing(s) be held in abeyand	e. See 37 CFR 1.85(a).	
Replacement drawing sheet(s) including the cor			
11) The oath or declaration is objected to by the	e Examiner. Note the attached	Office Action or form PTO-152.	
Priority under 35 U.S.C. § 119			
12) Acknowledgment is made of a claim for fore a) All b) Some * c) None of:  1. Certified copies of the priority docum 2. Certified copies of the priority docum 3. Copies of the certified copies of the papplication from the International But * See the attached detailed Office action for a	nents have been received. Idents have been received in Appriority documents have been reau (PCT Rule 17.2(a)).	plication No eceived in this National Stage	
Attachment(s)			
1) Notice of References Cited (PTO-892)		ımmary (PTO-413) /Mail Date	
<ol> <li>Notice of Draftsperson's Patent Drawing Review (PTO-948)</li> <li>Information Disclosure Statement(s) (PTO/SB/08)         Paper No(s)/Mail Date     </li> </ol>		ormal Patent Application	

Application/Control Number: 10/520,779

Art Unit: 1634

## **DETAILED ACTION**

## Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group 1, claim(s) 1-10, 19, 29-33 are drawn to method of detecting the presence or absence of markers linked to Alzheimer's. (Subject to further restriction)

Group 2, claim(s) 15-18 are drawn to oligonucleotide primers for the detection of Alzheimer's. (Subject to further restriction)

2. The inventions listed as Groups I and 2 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the invention is drawn to the detection of marker D12S1042 or D12S1057 that are indicative of Alzheimer's. Scott et al teaches the use of D12S1042 and D12S1057 as markers for Alzheimer's (Scott et al Am.J. Hum. Genet (2000) volume 66. pages 922-932). As the probes the invention is drawn were known in the art, the inventions lack a corresponding special technical feature over the prior art.

## **Further restriction**

Additionally, for groups 1 and 2 named above is subject to further restriction.

For group I, applicant is required to further elect a specific marker for claim 1, for examination.

For group I, applicant is required to further elect a chromosome segment for claim 7 and 19 corresponding to the marker selected for claim 1, for examination.

Application/Control Number: 10/520,779 Page 3

Art Unit: 1634

For group II, applicant is required to further elect a segment for claim 15 for examination.

This is NOT an election of species. Each marker and chromosome segment corresponds to a distinct nucleotide sequence. Each distinct nucleotide sequence and chromosome segment has a distinct nucleotide sequence and chemical composition, and is directed to detection of unique segments of chromosome 12. Thus each marker and chromosome segment are distinct. Each sequence is not obvious over the other sequences. Structurally distinct nucleotide sequences are distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequences are presumed to represent an independent and distinct invention, subject to restriction requirement pursuant to 35 USC 121 and 37 CFR 1.141. By statute, "[i]f two or more independent and distinct inventions are claimed in one application, the Commissioner may require the application to be restricted to one of the inventions." 35 U.S.C. 121. Pursuant to this statute, the rules provide that "[i]f two or more independent and distinct inventions are claimed in a single application, the examiner in his action shall require the applicant... to elect that invention to which his claim shall be restricted." 37 CFR 1.142 (a). See also 37 CFR 1.141(a). It is noted that searching more than one of the claimed patentably distinct sequences represents a serious burden for the office.

3. The examiner has required restriction between product and process claims.

Where applicant elects claims directed to the product, and the product claims are

subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder.

All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

4. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Steven C. Pohnert whose telephone number is 571-272-3803. The examiner can normally be reached on Monday-Friday 7:00-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Application/Control Number: 10/520,779 Page 6

Art Unit: 1634

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Steven Pohnert

JEANINE A. GOLDBERG PRIMARY EXAMINER